

**PRODUCT:** 672½ dozen bottles of *Vigorettes* at Buffalo, N. Y., in possession of Vigorettes, Inc., together with a number of display posters entitled "Now! New! More Potent Vigorettes" which were printed locally. The bottles were of various sizes, containing 30, 60, 90, 200, and 500 "capsulettes."

**LABEL, IN PART:** (Bottle) "Vigorettes Improved Added Potency Each Vigorette Capsulette Contains: Vitamin B<sub>1</sub> (Thiamine Hcl.) USP 5 mg., Vitamin B (Riboflavin) USP 5 mg., Vitamin B (Pyridoxine Hydrochloride) 0.5 mg., Vitamin C (Ascorbic Acid) 30 mg., Niacinamide USP 50 mg., Calcium Pantothenate 10 mg., Folic Acid USP 0.1 mg., Liver Desiccated NF 275 mg., Ferrous Gluconate (Equivalent to 20 mg. of Iron) 194.4 mg., Choline (Bitartrate) 15 mg., Inositol 10 mg., Vitamin B<sub>12</sub> (from streptomyces fermentations) 5 mcg., dl-Methionine 5 mg., Vitamin E 31 U., Iodine (from potassium iodide) 0.1 mg., Manganese (from manganese glycerophosphate) 1 mg., Cobalt (from cobalt sulfate) 0.1 mg., Zinc (from zinc sulfate) 1 mg., Magnesium (from magnesium sulfate) 2.5 mg., Potassium (from potassium sulfate) 2 mg., Molybdenum (from sodium molybdate) 0.2 mg. \* \* \* Dosage Adults: 1 or 2 Capsulettes daily."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements in the posters accompanying the article were false and misleading. The statements represented and suggested that the article when used as directed was effective in the treatment of anemia, nervousness, weakness, tiredness, poor digestion, heart trouble, migraine headaches, insomnia, tooth decay, pernicious anemia, coronary disease, and sterility, and that use of the article would insure better blood, steadier nerves, stronger and longer life, resistance to disease, better growth, healthy heart, healthy gums and teeth, pliant joints, healthy skin, good digestion, healthy liver, and proper muscle growth and tissue function. The article when used as directed was not effective in the treatment of such conditions, and it was not capable of fulfilling the promises of benefit made for it.

Further misbranding, Section 502 (c), the information required by Section 502 (e) (2), to appear on the label of the article, namely, the common or usual name of each active ingredient contained therein, was not prominently placed on the label with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use since it failed to distinguish between the active and inactive ingredients; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which the article was intended.

The article was alleged to be misbranded in the above respects while held for sale after shipment in interstate commerce.

**DISPOSITION:** May 16, 1952. Vigorettes, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency, and that the posters be destroyed.

**3769. Misbranding of Scientific Massage Modality devices and Stim-U-Lax Junior devices. U. S. v. 19 Devices, etc. (F. D. C. No. 32237. Sample Nos. 16400-L, 16401-L.)**

**LABEL FILED:** On or about December 18, 1951, Western District of Missouri.

**ALLEGED SHIPMENT:** On or about April 4 and August 1, 1951, by the John Oster Manufacturing Co., from Milwaukee, Wis.

**PRODUCT:** 19 *Scientific Massage Modality devices* and 5 *Stim-U-Lax Junior devices* at Kansas City, Mo., together with a number of leaflets entitled "Oster Scientific Massage Modality \* \* \* 360-A" and "Oster Stim-U-Lax Junior \* \* \* 644" and a booklet entitled "Massage An Aid to Better Health \* \* \* A-20095."

Each device consisted of a metal and rubber frame containing an electric motor which was mounted with an eccentric bearing at one end and a spring-held bearing at the other end, so that rotation of the motor caused the device to have a rapid vibratory motion.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements in the booklet and leaflets accompanying the devices were false and misleading. The statements represented and suggested that the devices were effective for providing better health; curing aches and pains; providing healing power; treating the sick and disabled; stimulating the circulation in the deeper tissues; helping remove and discharge waste products and tissue debris; soothing tense nerves; treating acute inflammation, sprains of joints, fractures of bones, and chronic inflammation; relaxing muscle spasm, as well as spasm of vessel walls; increasing the flow of blood and lymph; increasing local metabolic activity; promoting tissue repair; treating edema and obstructed venous return; helping to remove exudate and waste products; improving local nutrition; maintaining the general health of the body during a period of enforced fatigue; treating nerve prostration; maintaining the vitality and flexibility of parts that must be kept at rest for a long time; raising the blood pressure and increasing the amount of red and white blood cells; increasing the urine; stimulating the whole body; improving sleep; removing the waste products of fatigue; reducing swellings; stretching adhesions; loosening scars; loosening joints; acting on organs under the ribs; aiding nutrition of the tissues; discharging waste products and fatigue acids; soothing the nerves; relieving tension; helping the wasted body of convalescence to return to normal; treating overindulgence, lack of sleep, the "morning after" feeling, head and chest colds, and sinus conditions; reducing; keeping the teeth healthy; treating insomnia, nervousness, and headaches; providing vigor for elderly people; curing rheumatism; treating cramps; improving the condition of the scalp and hair; treating fractures, sprains, and dislocations; restoring muscle tone; reducing edema; treating sciatica and neuritis; giving health; and treating tired muscles, taut nerves, and a fagged worn-out feeling. The devices were not effective in the treatment of the conditions stated and implied, and they were not capable of fulfilling the promises of benefit made for them. The devices were misbranded in the above respects when introduced into and while in interstate commerce.

Further misbranding, Section 502 (f) (1), the labeling of the devices failed to bear adequate directions for use for the purposes for which they were intended, namely, arthritis, migraine headaches, rheumatism, cerebral hemorrhage, and polio, which were the conditions for which the devices were recommended orally by Mrs. Helen Moyer on behalf of the John Oster Manufacturing Co. The devices were misbranded in these respects while held for sale after shipment in interstate commerce.

**DISPOSITION:** June 2, 1952. The John Oster Manufacturing Co., claimant, having consented to the entry of a decree, judgment of condemnation was

entered and the court ordered that the devices be released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency. The above-mentioned booklet and leaflets subsequently were destroyed.

### DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3770. Supplement to notices of judgment on drugs and devices, No. 3652. U. S. v. Woodard Laboratories, Inc., and Dean D. Murphy and John L. Sullivan. Judgment of trial court affirmed on appeal. (F. D. C. No. 30053. Sample Nos. 29794-K, et al.)

Following the imposition of the sentences against the defendants, as reported in notices of judgment on drugs and devices, No. 3652, an appeal was taken by the defendants to the United States Court of Appeals for the Ninth Circuit. On August 29, 1952, the following opinion was handed down by that court, affirming the judgment of the lower court:

ORR, *Circuit Judge*: "This is an appeal from judgments of conviction on an information charging appellants with violation of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 301 et seq. Appellant Woodard Laboratories packaged and shipped in interstate commerce certain drugs manufactured by Crest Laboratories. Appellants Murphy and Sullivan are, respectively, president and general manager of Woodard Laboratories. The information charged the appellants in ten counts with five interstate shipments of alpha-estradiol tablets whose strength was below that declared on the labels; each shipment was the basis for two counts; one relating to adulteration and one to misbranding. 21 U. S. C. A. §§ 331 (a), 351 (c), and 352 (a). The District Court, sitting without a jury, found each of the defendants guilty on the five counts relating to adulteration. A total fine of \$2500 was imposed upon Woodard and a total fine of \$500 was imposed on each of the individual defendants.

"The tablets in question are shipped under the trade name 'Estrocrine' and contain alpha-estradiol, a female sex hormone which is dispensed only by or on the prescription of a physician. Samples of the tablets were subject to laboratory analysis by the Food and Drug Administration; the results of these assays led directly to the filing of the information. A drug distributor has an absolute liability for adulterated and misbranded drugs that he introduces into interstate commerce. 'Balancing relative hardships, Congress has preferred to place it on those who have at least the opportunity of informing themselves of the existence of the conditions imposed for the protection of the consumers before sharing in the illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.' United States v. Dotterweich, 320 U. S. 277, 285 (1943). The appellants contend, however, that the evidence was insufficient to sustain the judgment. A determination of this question requires a brief summarization of the evidence.

"Two witnesses testified for the Government. They are outstanding authorities in the general field of pharmaceutical chemistry and both have had a large experience in the study of estrogenic hormones.<sup>1</sup> They described in detail the methods of assay used in determining whether the Woodard tablets contained the 22 mcgs. of alpha-estradiol their labels represented the tablets to possess.

<sup>1</sup> Jonas Carol has been a chemist with the United States Food and Drug Administration for 21 years, and is chief of the Synthetic Branch of the Division of Pharmaceutical Chemistry. Practically all of his work has been in the analysis of drugs and in the development of methods for their analysis; during the past six years he has been engaged almost exclusively in developing methods for analysis of estrogenic hormones.

Dr. Daniel Banes has been a chemist with the Food and Drug Administration since 1939, specializing in drug analysis since 1940, and doing his chief work since 1948 on the analysis of estrogenic drug preparations.